In the Aftermath of *D'Arcy v. Myriad Genetics Inc*: Patenting Isolated Nucleic Acids in Australia

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On 7 October 2015 the High Court of Australia unanimously allowed the appeal on D'Arcy v. Myriad Genetics Inc and ordered that claims 1, 2 and 3 of Australian Patent No 686004, entitled "In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene", be revoked.

The High Court's judgment overturned the decisions of Justice Nicholas of the Federal Court, at first instance, and the Full Federal Court. This case note provides an overview of the High Court's decision and discusses its meaning and implications for patenting isolated nucleic acids in Australia.

I. *D'Arcy v. Myriad Genetics Inc* before the High Court of Australia

D'Arcy v. Myriad Genetics Inc concerns one of the gene patents, granted in the 1990s to Myriad Genetics ("Myriad"), in Australia[1] and in other countries. Myriad is a molecular diagnostic company founded in 1991, based in Salt Lake City (U.S.),[2] and the owner of several patents on DNA sequences of the BRCA1 and 2 genes,[3] which have been highly contested and legally challenged in the United States and in Europe. BRCA1 and 2 genetic mutations are linked to increased probabilities of developing breast and ovarian cancer. Myriad invested in research in this field and marketing of molecular diagnostic tests in order to establish genetic predisposition to these kinds of cancers and was granted product and method[4] patents, that covered DNA sequences of the BRCA1[5] and 2 genes, methods of diagnosis[6] and diagnostic kits.[7]

Associations of pathologists and geneticists, researchers and cancer patients, as well as NGOs and a political party, challenged Myriad's patents on different grounds in the United States[8] and Europe.[9]

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1 In Australia, Myriad was granted Aus. Patent No. 691958 "17q-linked breast and ovarian cancer susceptibility gene" and Aus. Patent No. 686004 "In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene", which was challenged in *D'Arcy v. Myriad Genetics Inc*.

2 On Myriad's foundation, see Myriad's history webpage, available on the Internet at <https://www.myriad.com/about-myriad/inside-myriad/history/ > (last accessed on 15 March 2016).

3 The BRCA1 gene was discovered in 1990, and is a tumor-suppressor gene, linked to genetic breast and ovarian cancer. Women who have a mutation of this gene tend to have a high incidence of breast cancer, as well as ovarian cancer. In 1995 the BRCA2 gene was mapped and sequenced. While BRCA1 affects only women and also carries an increased risk of ovarian cancer, BRCA2 raises the risk of breast cancer alone, and it can affect both women and men. Guido De Wert, Ruud Ter Meulen, Roberto Mordacci and Mariachiara Tallacchini, *Ethics and Genetics. A Workbook for Practitioners and Students* (Oxford-New York: Berghahn Books, 2003). On the discovery of BRCA1 and 2 genes see also Shobita Parthasarathy, *Building Genetic Medicine. Breast Cancer, Technology, and the Comparative Politics of Health Care* (Cambridge MA: The MIT Press, 2007), at pp. 3-7.

4 In the United States the "product category" of the challenged patents before the Courts included: (a) claims that covered the isolated BRCA genes (claim 1 of the '282 patent, claim 1 of the '473 patent, and claims 1 and 6 of the '492 patent); (b) claims that covered only the BRCA cDNA (claims 2 and 7 of the '282 patent and claim 7 of the '492 patent); claims that covered portions of the BRCA genes and cDNA as small as 15 nucleotides long (claims 5 and 6 of the '282 patent). The "method category" encompassed method claims directed at comparing or analyzing a patient's altered BRCA sequence with the normal one or wild-type one to identify the presence of cancer-predisposing mutations (e.g. claim 1 of the '999 and '001 patents)

5 For example, Aus. Patent No. 686004.

6 For example, European Patent EP699754.

7 For example, European Patent EP705902.

8 In the United States the Association of Molecular Pathology (AMP), The American College of Medical Genetics (ACMG), The American Society for Clinical Pathology (ASCP), The College of American Pathologists (CAP), several cancer researchers and genetic counselors, as well as some women potentially carrying BRCA1 and 2 mutated genes.

9 On the opposition to Myriad's patents concerning BRCA1 and 2 genes, see Jordan Paradise, "European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy", 59 *Food &*

They questioned its patents on legal and technical grounds, but they raised also some policy concerns. They claimed that Myriad's patents and its monopolistic market strategy were hindering research on genetic diagnosis, raising the cost of clinical diagnostic tests for hereditary cancer susceptibility and reducing access to these tests for patients (restraining, thus, access to health care). Moreover, they maintained that Myriad's intellectual property was impinging on the quality of tests, as researchers willing to improve the accuracy and reliability of tests on BRCA1 and 2 mutations could not have access to the DNA sequences without infringing Myriad's patents.

Several Myriad's patents claims were revoked by the European Patent Office (EPO)[10] and by the United States Patent and Trademark Office (USPTO), following the decision of the United States Supreme Court in 2013.[11] On 26 November 2010, also in Australia revocation proceedings, regarding the validity of a fundamental Myriad's patent on BRCA1, initiated and the decision of the High Court of Australia in *D'Arcy v. Myriad Genetics Inc* concludes a long judicial battle.

On 7 October 2015 the High Court of Australia unanimously allowed the appeal on *D'Arcy v. Myriad Genetics Inc*[12] ("the D'Arcy case" or "*D'Arcy*") and ordered that claims 1, 2 and 3 of Australian Patent No 686004 be revoked. The High Court set aside paragraph 1 of the order of the Full Court of the Federal Court of Australia, made on 5 September 2014.[13] Although the Justices of the High Court agreed on the order, they expressed three different opinions about why these claims on nucleic acids[14] should not be considered patentable subject matter under section 18 of the *Patents Act* 1990 (Cth).

Yvonne D'Arcy ("D'Arcy"), a former breast cancer patient, and Cancer Voices Australia, an alliance of cancer consumer organizations which works on national issues for Australians affected by cancer,[15] initiated revocation proceedings before the Federal Court of Australia,[16] challenging the validity of claims 1, 2 and 3 of Australian Patent No 686004 under s 138 of the *Patents Act*, on the ground that the invention was not patentable.[17] Myriad Genetics Inc (first respondent) filed on 11 August 1995 and was granted Australian Patent No 686004 patent, which was exclusively licensed to Genetic Technologies Ltd (second respondent).

The challenged patent regards "in vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene" and consists of 30 claims, but only the first three claims were at issue before the High Court. These claims are directed to:

1. "An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.
2. An isolated nucleic acid as claimed in claim 1 which is a DNA coding for a mutant BRCA1 polypeptide, said DNA containing in comparison to the BRCA1

Drug Law Journal (2004), pp. 133 et sqq. See also Gert Matthijs and Gert-Jan B. Van Ommen, "Gene Patents: From Discovery to Invention. A Geneticist's View", in Geertrui Van Overwalle (ed.), *Gene Patents and Collaborative Licensing Models. Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge: Cambridge University Press, 2009), pp. 311 et sqq.

10 Jordan Paradise, "European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy", cit., at pp. 138 et sqq.

11 Supreme Court of the United States, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, 13 June 2013, 569 U.S. 12-398 (2013), available on the Internet at <http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf> (last accessed 15 March 2016).

12 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, available on the Internet at <http://eresources.hcourt.gov.au/downloadPdf/2015/HCA/35> (last accessed on 15 March 2016).

13 Full Court of the Federal Court of Australia, *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115, 107 IPR 478.

14 The term "an isolated nucleic acid", as defined in the complete specification, includes DNA, RNA or a mixed polymer, "which is substantially separated from other cellular components which naturally accompany a native human sequence or protein". See High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 2.

15 See Cancer Voices Australia's website, available on the Internet at <http://www.cancervoicesaustralia.org/about-us/ > (last accessed on 15 March 2016).

16 Federal Court of Australia, *Cancer Voices Australia and Another v Myriad Genetics Inc and Another*, 15 February 2013, [2013] FCA 65, 99 IPR 567.

17 Section 138(3)(b) of *Patents Act* 1990 sets out as ground of revocation "that the invention is not a patentable invention". *Patents Act* 1990 (Cth), s 138(3)(b), available on the Internet at <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s138.html> (last accessed on 15 March 2016).

polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations set forth in Tables 12, 12A and 14.

3. An isolated nucleic acid as claimed in claim 1 which is a DNA coding for a polymorphic BRCA1 polypeptide, said DNA containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more polymorphisms set forth in Tables 18 and 19".[18]

The patent concerns the field of human genetics and "relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposition gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular, breast and ovarian cancer".[19]

At first instance, Justice Nicholas of the Federal Court of Australia dismissed the application challenging the validity of these claims, holding that "isolated nucleic acid, with the same chemical composition and structure as found in human cells, constitutes an artificial state of affairs, such that it is patentable matter".[20] Justice Nicholas pointed out that the isolation of the nucleic acids results from human intervention, "such that the isolated nucleic acid does not exist in the same way as it does in human cells".[21] Moreover, he highlighted that "immense research and intellectual effort" is involved in the isolation of nucleic acids. Therefore, he deemed the disputed claims valid, as a "manner of manufacture" within the meaning of s 18(1)(a) of the *Patents Act* 1990.

On appeal the Full Court of the Federal Court of Australia affirmed and held that "the isolated nucleic acid is an artificial state of affairs because it is removed from the genome and the cell".[22] The Full Court maintained that the disputed isolated nucleic acids are chemically, structurally and functionally different from the naturally occurring polynucleotides.[23] Moreover, the Full Court concluded that, since the isolation of nucleic acids entails an economically useful result, the treatment of breast and ovarian cancer, it falls within the definition of a manner of manufacture and the claimed product is patentable under s 18 of the Patents Act 1990.[24]

II. The Arguments of the High Court of Australia

The High Court of Australia judged that claims 1, 2 and 3 of patent No 686004 should be revoked as they did not fall within the definition of patentable invention under s 18(1) of the Patents Act 1990. The appellant, Yvonne D'Arcy, asked for the revocation of the claims under s 138(3)(b), namely on the grounds that "the invention is not a patentable invention".[25]

Section s 18(1)(a) of the *Patents Act* 1990 provides that:

"Subject to subsection (2), a patentable invention is an invention that, so far as claimed in any claim:

(a) Is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies".[26]

Moreover, the section sets out the requirements of novelty, inventive step and usefulness and no secret user before the priority date, which were not raised, however, in the appeal before the High Court.[27]

An "invention" is, according to the Dictionary in Sched 1 to the *Patents Act* 1990, "any manner of new manufacture the subject of letters patent and grant

18 Australian Patent No 686004, "In vivo mutations and Polymorphisms in the 17q-linked breast susceptibility gene", available on the Internet at <http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do;jsessionid=1hyrWyKdDdtMTG4qJL31qJLpx3yfrpj9MJch7ZTpCQ7ctskbhhlp!-1718864290>.

19 Australian Patent No 686004, "In vivo mutations and Polymorphisms in the 17q-linked breast susceptibility gene", *supra* note 18, at p. 1.

20 Federal Court of Australia, *Cancer Voices Australia and Another v Myriad Genetics and Another*, 15 February 2013, [2013] FCA 65, 99 IPR 567.

21 Federal Court of Australia, *Cancer Voices Australia and Another v Myriad Genetics and Another*, 15 February 2013, [2013] FCA 65, 99 IPR 567.

22 Full Court of the Federal Court of Australia, *D'Arcy v Myriad Genetics and Another*, 5 September 2014, [2014] FCAFC 115, 107 IPR 478.

23 Full Court of the Federal Court of Australia, *D'Arcy v Myriad Genetics and Another*, 5 September 2014, [2014] FCAFC 115, 107 IPR 478.

24 Full Court of the Federal Court of Australia, *D'Arcy v Myriad Genetics and Another*, 5 September 2014, [2014] FCAFC 115, 107 IPR 478.

25 *Patents Act* 1990 (Cth), s 138(3)(b), available on the Internet at <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s138.html> (last accessed on 15 March 2016).

26 *Patents Act* 1990 (Cth), s 18(1)(a), available on the Internet at <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s18.html> (last accessed on 15 March 2016).

27 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, available on the Internet at <http://eresources.hcourt.gov.au/downloadPdf/2015/HCA/35> (last accessed on 15 March 2016), at p. 7.

of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention".[28]

The High Court pointed out that the inquiry over the patentability of the invention should focus on the "impugned claims read in the light of the specification as a whole and the relevant prior art"[29] and that any claim must satisfy the conditions of patentability under s 18(1). Recalling Lord Russell of Killowen's clarification of the function of patent claims,[30] the Court highlighted the limiting role of claims, that should define "clearly and with precision the monopoly claimed" so to allow others to know its precise boundaries, and that the boundary function of the claims is also mandated by s 40(2)(b) of the *Patents Act*.

The court had, first, to address whether the challenged invention was a "manner of manufacture" within the meaning of Section 6 of the Statute of Monopolies, which provides all monopolies to be void safe for:[31]

> "Letters Patents and Grants of Privilege for ... the sole working or making of any matter of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the time of making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising prices of Commodities at home, or hurt of Trade, or generally inconvenient ...".[32]

Whereas section 18(1)(a) of the *Patents Act* 1990 requires that a patentable invention must be "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies",[33] *National Research Development Corporation v Commissioner of Patents* ("*NRDC*"), decided in 1959 by the High Court, sets out the meaning of the term "a manner of manufacture". In *NRDC*, the High Court upheld the validity of a patent on a method which used two known chemical compounds for new herbicidal purposes.[34] The Court argued about the method that:

> "The effect produced by the appellant's method exhibits the two essential qualities upon which 'product' and 'vendible' seem designed to insist. It is a 'product' because it consists in *an artificially created state of affairs* discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is *economic* (...)".[35]

Interpreting the terminology used in *NRDC*, namely "artificially created state of affairs of economic significance", the High Court explained that this formula should not be considered exhaustive of the concept "manner of manufacture". Conversely, *NRDC* endorsed the view that the terminology "manner of manufacture" had to be considered a concept for a case-by-case development, mandating a common law methodology.[36]

The High Court pinpointed that a number of factors are relevant in determining whether the exclusive patent rights should be extended to a specific class of claims. *NRDC* decision established two factors to be considered in order to characterize the invention as a "manner of manufacture": "1. whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action. 2. Whether the invention as claimed has economic utility".[37] The Court deemed that these factors are ordinarily sufficient to judge if the invention falls within the concept of "manner of manufacture" as developed by case law. However, when a new class of claims entails a significant extension or new application of this concept, other important factors

28 The *Patents Act* 1990, Sched 1, definition of "invention", available on the Internet at <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/sch1.html> (last accessed on 15 March 2016).

29 High Court of Australia, D'Arcy v Myriad Genetics Inc, 7 October 2015, [2015] HCA 35, 115 IPR 1, *supra* note 12, at p. 8.

30 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 8-9.

31 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 3.

32 *Statute of Monopolies*, s 6, 21 Jac I c 3 (1624).

33 On the meaning and background of the term "manner of manufacture" in Australian patent law, see Mark J. Davison, Ann L. Monotti, Leanne Wiseman, *Australian Intellectual Property Law*, 3rd ed. (Port Melbourne AU: Cambridge University Press, 2016), at pp. 456-463.

34 On the decision of the High Court of Australia in *NRDC* and its impact on Australian patent law see Stephen Hubicki and Brad Sherman, "We Have Never Been Modern: the High Court's Decision in *National Research Development Corporation v Commissioner of Patents*", in Andrew T. Keyton, Megan Richardson and Sam Ricketson (eds), *Landmarks in Australian Intellectual Property Law* (Cambridge: Cambridge University Press, 2009), pp. 73 et sqq.

35 *National Research Development Corporation v Commissioner of Patents*, (1959) 102 CLR 252, at p. 277. Emphasis added.

36 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 3 and 15.

37 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 18.

should be taken into consideration. The Court listed some factors related to the *Patents Act* and its purposes, such as:

> "3.1. whether the invention as claimed, if patentable under s 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;
> 3.2. whether the invention as claimed, if patentable under s 18(1)(a), could, because of the content of the claims, have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;
> 3.3. whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.
> 4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability".[38]

Furthermore, the Court numbered other criteria: "5.1. Australia's obligations under international law; 5.2. the patent laws of other countries; 6. whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by legislature".[39]

Factors 3, 4 and 6 were judged of primary relevance and the decision largely hinges on them. The Justices also considered the other factors. They, however, rejected Myriad's argument that, by failing to grant patentability to inventions such as these, Australia would breach and not comply with its international legal obligations under article 27(1) of the *TRIPs Agreement*. Article 27(1) of the *TRIPs Agreement* requires that, "subject to the provisions of paragraph 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".[40] They clarified that an international obligation to recognize as inventions the subject matter of the claims could not rest on the materials and submissions before the Court.[41]

Moreover, they dismissed the relevance of patent legislative history, which did not support any implied exclusion of isolated DNA or RNA sequences from patentability, pinpointing that the question before the Court did not concern gene patenting at large, but whether the invention as claimed fell within the established application of "manner of manufacture".[42] The different patent laws of other jurisdictions were deemed irrelevant, as they argued that, notwithstanding the efforts of patent law harmonization, the new questions of patentability must be determined judicially on a case-by-case basis.[43]

The High Court, then, challenged Myriad's characterization of the subject matter of its patent claims as for a product, which is a *chemical compound*, contending that, conversely, the nucleotide sequences should be properly described as *information*. Myriad's identification of the subject matter of the claims, endorsed by the Full Court, was censured on the grounds that this premise "elevates form over substance to the detriment of the developmental function entrusted to the Court as explained in *NRDC* and reflected in the continuing use of the 'manner of manufacture' formula in s 18(1)(a) of the Act".[44]

Focusing on the *substance* of the claims, the Court pointed out that it is the existence of that information which is the fundamental element of the invention as claimed, concluding that "the product is the medium in which that information resides".[45] As the information "stored in the sequence of nucleotides coding for the mutated or polymorphic BRCA polypeptide is the same information as that contained in the DNA of the person from which the nucleic acid was isolated"[46] and is not actually "made", the claims were deemed to lie at the boundaries of the concept of "manner of manufacture".

The High Court, therefore, gave prominence to the informational dimension of the nucleic acids, dis-

38 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 18-19.

39 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 19.

40 World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* or *TRIPs Agreement*, art. 27 *Patentable Subject Matter*, available on the Internet at <https://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5> (last accessed on 15 March 2016).

41 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 21.

42 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 24.

43 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 23.

44 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 41.

45 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 42.

46 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 41-42.

missing Myriad's characterization of the claims. The Justices expressed concerns that the very large and unquantified size of the class of the claimed nucleic acids, which bear the information, raised the risk of a *chilling effect* on the "legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and investors".[47]

Compared to the opinion issued by the majority of the High Court (Justices French, Kiefel, Bell and Keane), Justices Gageler and Nettle agreed on the order, but focused on whether the subject matter of the claims was sufficiently artificial and inventive to be regarded as patentable. They explained that the artificiality of a product can be inferred from a number of factors, such as "the labour required to create it"[48] and "the physical differences between it and the raw material from which it is derived".[49] Justices Gageler and Nettle, however, pointed out that, regardless of these factors, it is necessary that inventiveness makes a contribution to the essential difference between the product and nature. Recalling several cases[50] in which it was held that the subject matter of the claims as disclosed in the specification must possess a quality of inventiveness, they argued that Myriad's disputed claims lacked inventiveness: "insofar as the invention consists in the application of a naturally occurring phenomenon to a particular use the inventor cannot claim to have invented the naturally occurring phenomenon as opposed to the method of use and has no claim to a monopoly over the naturally occurring phenomenon as opposed to the method of use".[51] They maintained that the way in which a claim is drafted cannot transcend the reality of what is in suit. As Myriad did not invent the process for isolating nucleic acids or amplifying DNA sequences for genetic testing, the invention consisted in "no more than the application of a recognized existing technique to a known purpose of examining fragments of human DNA".[52] They, therefore, concluded that the claims did not fall within the definition of "a manner of manufacture" for a product, namely "an artificial thing or state of affairs which involves an element of inventiveness".[53]

Justice Gordon concurred, but framed the issue before the High Court in terms of the definition of invention. He observed that the primary requirement of a patentable invention "is that it be an invention"[54] and, thus, focused his analysis on the identification of the subject matter of the disputed claims. Analyzing claim 1, as claims 2 and 3 were deemed a subset of it,[55] Justice Gordon contended that it was not a claim to a patentable product for several reasons: no single product was identified but multiple ones, Myriad could not delineate the bounds of the class of chemical compounds by reference to a chemical composition of every possible product and, moreover, did not create, make or alter the characteristics of the code.[56] He, consequently, judged claims 1-3 lacking invention.[57]

III. Comment

Following the High Court's judgment in *D'Arcy v Myriad Genetics Inc*, on 16 October 2015 the Australian Patent Office issued a draft Examination Practice for public consultation,[58] which was applied immediately to pending patent applications.[59] After its publication, the Commissioner of Patents undertook the con-

47 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 43.

48 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 53.

49 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 53.

50 Full Court, *Commissioner of Patents v Microcell Ltd*, (1959) 102 CLR 232; [1959] HCA 71. *N V Philips Gloeilampenfabrieken v Mirabella International Pty Ltd*, (1995) 183 CLR 655, at pp. 663-665 per Brennan, Deane and Toohey; [1995] HCA 15.

51 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 57.

52 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 67.

53 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 66-67.

54 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 80.

55 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 82.

56 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at pp. 83 and 90.

57 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 90.

58 Australian Patent Office, "Examination Practice Following the High Court Decision in D'Arcy v Myriad Genetics Inc", available on the Internet at <http://www.ipaustralia.gov.au/pdfs/consultaiton_submissions/20151214_Examination_practice_following_the_High_Court_decision_in_D'Arcy_v_Myriad_Genetics_Inc.pdf> (last accessed on 15 March 2016), pp. 1 et sqq.

59 Australian Government-IP Australia, *News, Events and Publications*, available on the Internet at <http://www.ipaustralia.gov.au/about-us/news-media-and-events/latest-news-listing/examination-practice> (last accessed on 15 March 2016).

sultation process[60] and changes to the Manual of Practice and Procedure were made on 11 January 2016 regarding the Principles for Examination[61] and, in particular, Nucleic Acids and Genetic Information.[62] Although the High Court explained that the decision did not concern gene patenting, *D'Arcy* has implications for the definition of patent "eligible subject matter" and its scope.

The patentability of genes in Australia largely hinged on the decision by the Australian Patent Office,[63] in 1995, in *Kirin-Amgen Inc v Board of Regents of University of Washington*.[64] In the aftermath of *Kirin-Amgen Inc*, a long-standing practice of granting patents on isolated gene sequences has been established. At present, this practice is undergoing important changes under the revised examination practice.

The examination practice recommends that consideration should be given to the extent to which the claimed invention in *substance* "falls within established categories of eligible subject matter".[65] Otherwise patent examiners ought to address whether other considerations expressed by the High Court must be applied.

The Australian Patent Office clarified that, in order to tackle these issues, there are four main questions to be dealt with: "1. What is the substance of the claim? 2. "Has the substance of the claim been 'made' or changed by man? 3. Does the invention have economic utility? 4. Does the invention as claimed represent a new class of claim?".[66]

The first step consists in identifying the substance of the claims. The Patent Office specified a list of factors that should be considered, such as: the form of words and breadth of the claim; the size of the class of compound covered by the claim; whether the compound embody or convey information that is of importance to the utility of the claimed invention; the emphasis of the claims; what did the applicant invent.[67]

The second step aims at assessing whether the substance is "made" and entails a comparison between the state of affairs before the invention and the one as a result of it. This assessment requires the examiner to consider whether the substance of the claim was "made" (i.e. created or modified by human action), what was the labour required to produce the product and what are the physical differences between the claim and the natural state. However, the Patent Office clarified that "isolation and purification can represent making or modification when the substance of the claim is properly directed to a chemical product".[68]

The third step involves establishing the existence of the requirement of economic utility, set out in *NRDC*.[69]

If a claim seems to relate to a new class (step four), which implies "a significant new application or extension of the principles of patentability",[70] other factors should be pondered: which categories of alleged inventions the Courts have been involved with and whether the subject matter was rejected. The examination practice specifies the technical subject matter which has not been rejected by Courts: recombinant or isolated proteins; pharmaceuticals and other chemical substances; methods of treatment; methods of applying herbicides; applications of computer technology. Subject to other requirements, patents on this matter are, therefore, available.[71]

The Manual of Practice and Procedure then explains that, where the claimed invention entails a significant new application or extension of "manner of

60 The Commissioner of Patents invited all the interested parties to make submissions by 6 November 2015. Australian Government-IP Australia, *Public Consultations*, available on the Internet at <http://www.ipaustralia.gov.au/about-us/public-consultations/Revised-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/> (last accessed on 15 March 2016).

61 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", available on the Internet at <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> (last accessed on 15 March 2016).

62 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.2.6 Nucleic Acids and Genetic Information", available on the Internet at <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> (last accessed on 15 March 2016).

63 David P. Simmons and Mark E. Wickham, "Gene Patents in Australia: Where Do We Stand?", 30 *Nature Biotechnology* (2012), at p. 232.

64 *Kirin-Amgen Inc v Board of Regents of University of Washington*, (1995) 33 IPR 557.

65 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

66 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

67 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

68 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

69 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

70 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

71 Australian Patent Office, *Manual of Practice and Procedure*, "2.9.1 Principles for Examination", *supra* note 61.

manufacture", the six factors indicated by the High Court would require consideration.[72]

D'Arcy v Myriad Genetics Inc is already affecting the Australian Patent Office's examination practice and legal scholars have tried to understand to what extent it will impinge on several kinds of patent claims.[73] Nevertheless, the High Court's decision can be understood only considering some scientific and epistemological issues which, together with economic ones, are intertwined with patenting genes.

The influential historian of the life sciences Hans-Jörg Rheinberger, together with other biologists,[74] showed that "the spectacular rise of molecular biology has come about without a comprehensive, exact, and rigid definition of what a gene is".[75] In particular, Rheinberger illustrated that:

> "This claim can be substantiated for both aspects distinguishing the gene concept of molecular biology from that of classical genetics: the aspect of representing a material entity, and that of being a carrier of information.[76] The meaning of both these notions has remained fuzzy and tied to the experimental spaces that the new biology was going to explore, from the identification of DNA as the hereditary material in bacteria in 1944 to the genome sequencing projects of the late 1980s".[77]

He pointed out that the gene is a "boundary object",[78] namely "an analytic concept of those scientific objects which both inhabit several intersecting social worlds (...) and satisfy the informational requirements of each of them".[79] Boundary objects, such as the atom in physics and the molecule in chemistry, he observed, are provided with "organizing power" in research fields and "are embedded in experimental operations".[80] Within molecular biology the "gene" underwent several shifts of meaning:

> "At the beginning, molecular genetics, with its set of biochemical practices and genetic manipulations, was characterized by switching from higher plants and animals to bacteria and phages as model organisms. First, it transformed its boundary object, the gene, into a *material physicochemical entity*. Second, it has made a unit endowed *with informational qualities* from the object. The first transformation provided a solution to the problem that classical genetics had with the stability of its units. The answer was: Genes consist of metastable macromolecules of such as nucleic acids. The second transformation provided a solution to the problem that classical genetics had with its units' mode of reproduction, and the connection between genotype and phenotype. The answer was: Nucleotide sequences, and DNA in particular, can be replicated specifically and faithfully by virtue of the stereochemical properties of their building blocks".[81]

As the legal scholar Brad Sherman pinpointed, "the process of determining whether subject matter is patent-eligible is essentially an exercise of labeling, classifying, and categorizing".[82] As far as patent litigation is concerned, isolated genes and nucleic acids can be defined either as material chemical entities and/or carriers of information. Since each of these characterizations and definitions of the genes can be

72 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, available on the Internet at <http://eresources.hcourt.gov.au/downloadPdf/2015/HCA/35> (last accessed on 15 March 2016), at pp. 18-19.

73 Kim O'Connell and James Ellsmore, "Isolated Nucleic Acid Sequences No Longer Patentable in Australia: *D'Arcy v Myriad Genetics Inc*", 15 *Bio-Science Law Review* (2016), pp. 25 et sqq., at pp. 29-30.

74 Thomas Fogle, "The Dissolution of Protein Coding Genes in Molecular Biology", in Peter Beurton, Raphael Falk and Hans-Jörg Rheinberger (eds), *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2003), pp. 3 et sqq.

75 Hans-Jörg Rheinberger, "Gene Concepts. Fragments from the Perspective of Molecular Biology, in Peter Beurton, Raphael Falk and Hans-Jörg Rheinberger (eds), *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2003), pp. 219 et sqq., at p. 221.

76 Sahotra Sarkar, "Biological Information: A Skeptical Look at Some Central Dogmas of Molecular Biology", in Sahotra Sarkar (ed.), *The Philosophy and History of Molecular Biology: New Perspectives* (Dordrecht: Kluwer Academic Publishers, 1996), at p. 187.

77 Hans-Jörg Rheinberger, "Gene Concepts. Fragments from the Perspective of Molecular Biology, *supra* note 75, at p. 221.

78 Susan Leigh Star and James R. Griesmer, 'Institutional Ecology, Translations and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology 1907-1939', 19 *Social Studies of Science* 387.

79 Susan Leigh Star and James R. Griesemer, "Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-38", *supra* note 78, at p. 393.

80 Hans-Jörg Rheinberger, "Gene Concepts. Fragments from the Perspective of Molecular Biology, *supra* note 75, at p. 220.

81 Hans-Jörg Rheinberger, "Gene Concepts. Fragments from the Perspective of Molecular Biology, *supra* note 75, at p. 221. Emphasis added.

82 Brad Sherman, "*D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia", 37 *Sydney Law Review* (2015), pp. 135 et sqq., at p. 136.

used to suggest and endorse opposite prescriptive conclusions about their patentability, which view the judges opt for results crucial in courts' decisions regarding this kind of subject matter. It has been suggested that Australian patent law "lacks the tools and techniques to categorise subject matter: at least in a way that does not appear arbitrary and capricious"[83] and, therefore, the High Court was expected to fill this vacuum and clarify, at least, which criteria should be applied in order to establish whether isolated DNA differs from naturally occurring DNA or not.[84]

The legal scholar James Boyle explained, referring to the contemporary "information society" and economy, that they are marked by "the tendency toward the economic and conceptual separation of the informational message from the medium – cells, diskettes, telephone, directories or whatever – and of the progressive devaluation (literally, the diminishing marginal cost) of the medium as compared with the message".[85] Boyle illustrated that, although information is embedded in a medium, the economic value lies in the information itself.

The High Court's decision should be read in the light of these remarks. It focused on the *substance* of the patented claims, showing that they were directed not to isolated nucleic acids as *chemical compounds*, as Myriad's argued, but to isolated nucleic acids as *information*. The Court drew this conclusion from the terms in which the claims were expressed, implicitly pointing out and recalling that it is the information carried by nucleic acids which is valuable and patent protection is sought for and directed to it.

D'Arcy ultimately involved genetic information and its fundamental value for cancer patients, researchers and medical practitioners, as well as companies investing in developing molecular diagnostic tests. The decision rested on concerns about the "real risk that the chilling effect of the claims, on the use of any isolation process in relation to the BRCA1 gene, would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the BRCA1 protein"[86] and its potential consequences for innovation in molecular diagnostics.

83 Brad Sherman, "*D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia", *supra* note 82, at p. 144.

84 Brad Sherman, "*D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia", *supra* note 82, at p. 144.

85 James Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (Cambridge MA: Harvard University Press, 1997), at p. 7.

86 High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, *supra* note 12, at p. 5.